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EPA CANNOT KEEP PHOSMET ON THE EXTREMELY HAZARDOUS SUBSTANCE LIST WHEN AVAILABLE DATA DO NOT DEMONSTRATE THAT PHOSMET MEETS THE LISTING CRITERIA

- ***EPA Has Indicated on Numerous Occasions That There Are No Data Showing That Phosmet Meets the Listing Criteria***

  - EPA's 1997 Draft Evaluation of Phosmet makes clear that phosmet does not meet the main listing criteria. It states:

    > The only data indicating that phosmet meets the EHS criteria for listing are inhalation toxicity (LC_{50}) data that cannot be verified. These data come from a Russian reference and are based on pre-1977 Russian studies that are not available for review. In addition, the reference includes a chemical structure that is not correct for phosmet, raising questions about the identity of the chemical studied.[1]

  - EPA staff indicated on numerous occasions over the past eight months that EPA planned to propose delisting phosmet because no data showed that phosmet meets the listing criteria.

- ***EPA Must Delist Phosmet Consistent with the Law and EPA's Historic Practice***

  - EPA has delisted a number of substances from the EHS list when it has found that the basis for the original listing was in error and other studies either did not show toxicity or showed that the substance did not meet the toxicity criteria for listing.[2]

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1 "Draft Evaluation of Phosmet Delisting Petition Submitted by Gowan Company (1996)" (Mar. 31, 1997) at 9, prepared by ICF Consulting Group.

2 55 Fed. Reg. 5544 (Feb. 15, 1990) (EPA removed dimethyl sulfide, isopropyl formate, methyl disulfide, phenol 2,2'-thiobis(4,6-dichloro-), piprotal, and sodium pentachlorophenate from the list of EHSs after reviewing the available toxicity data for these chemicals and concluding they do not meet the listing criteria); 61 Fed. Reg. 20473 (May 7, 1996) (EPA removed phosphorous pentoxide, diethylcarbamazine citrate, fenitrothion, and tellurium from the EHS list because review of the available toxicity data shows they do not meet the listing criteria).

➢ In *A.L. Laboratories v. EPA*, the District Court for the District of Columbia held that EPA may not decline to delete substances incorrectly included on the initial EHS list based on invalid data, in the absence of other existing data demonstrating the acute toxicity criteria are met.[3]

- The court rejected EPA's determination that Section 302 of EPCRA precluded the Agency from removing any chemical initially listed until the short-term and long-term effects which may result from a short-term exposure to such chemical have been determined and evaluated.[4]

- The court further found that "section 11002(a)(4) [Section 302] makes sense only when applied to substances for which evidence of toxicity *exists* and *supports* their appearance in the Right-to-Know list."[5] Thus, the court makes clear that sufficient evidence must exist to support a listing at the time of the listing and does not permit listing to continue until some future point after new data are developed and evaluated.

- Finally, the court notes that vague allegations by EPA that some evidence of toxicity exists do not suffice for refusing to delist and that "no reasonable jury could find from these allegations that [either of the substances at issue] is extremely hazardous."[6] A proposal for new testing does not even constitute vague allegations -- rather it is a mere proposal to take future steps.

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3 *A.L. Labs. v. EPA*, 674 F. Supp. 894, 899-900 (D.D.C. 1987).

4 *Id.* at 899-900.

5 *Id.* at 900 (emphasis added).

6 *Id.*

- The *A.L. Labs* conclusions are consistent with the standard under the EPCRA Section 313 delisting criteria, which also does not require new data to show that a current listing is not valid. In *Troy v. Browner*, 120 F.3d 277, 293 (D.C. Cir. 1997), the U.S. Court of Appeals for the D.C. Circuit found EPA's decision to list DMP under EPCRA Section 11023 (the TRI list) based "on tests that were largely undocumented violates the agency's Guidelines and evidences arbitrary and capricious agency action."[7] The court accordingly remanded the case to the district court with instructions to remand the case to EPA "for further proceedings consistent with this opinion." This instruction clearly was not intended to allow EPA time to develop new data that met the EPA Guidelines for listing.

■ ***EPA's Stated Intent to Generate Acute Toxicity Data Must Comply with the ICCVAM Authorization Act of 2000***

- ICCVAM states that each federal agency that "recommends or requires acute or chronic toxicological testing" must "ensure that any new or revised acute or chronic toxicity test method, including animal test methods and alternatives, is determined to be valid for its proposed use prior to requiring, recommending, or encouraging the application of such test method."[8]

- ICCVAM further seeks to eliminate unnecessary animal testing, which is also an EPA stated goal.

- Any testing not clearly mandated and involving animals would violate clear ICCVAM goals, and disregard EPA's own stated commitment to

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7 The EPA Guidelines in question required EPA "to base listing decisions on laboratory tests that 'follow an acceptable standard protocol.'" 120 F.3d at 293.

8 ICCVAM, Pub. L. 106-545, Section 4(c), available at http://iccvam.niehs.nih.gov/about/PL106545.pdf.

"avoiding unnecessary . . . animal testing."[9] It also ignores EPA's own recognized "important role" in the ICCVAM.[10]

9 65 Fed. Reg. 78746, 78749 (Dec. 15, 2000).

10 *See* 65 Fed. Reg. at 78746-47.

Phosmet Acute Toxicity Profile

Route of Exposure	Acute Toxicity Trigger	Preferred Test Species*	Phosmet Data	Remarks
Oral	$\leq$ 25 mg/kg	Rat	113 - 304 mg/kg	Results from several studies
Dermal	$\leq$ 50 mg/kg	Rabbit	> 3,160 mg/kg - > 5,000 mg/kg	Results from several studies
Inhalation	$\leq$ 0.5 mg/L	Rat	N/A	It is not possible to generate a respirable aerosol with technical phosmet

* Per OPPTS Harmonized Guidelines, 1998.